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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/650,326	08/28/2003	Keith A. Hruska	STK-P01-599	6882

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ROPES & GRAY LLP
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EXAMINER

BORGEEST, CHRISTINA M

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1649

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09/29/2009

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Advisory Action Before the Filing of an Appeal Brief	Application No. 10/650,326	Applicant(s) HRUSKA ET AL.	
	Examiner Christina Borgeest	Art Unit 1649	

--The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

THE REPLY FILED 03 September 2009 FAILS TO PLACE THIS APPLICATION IN CONDITION FOR ALLOWANCE.

1. ☐ The reply was filed after a final rejection, but prior to or on the same day as filing a Notice of Appeal. To avoid abandonment of this application, applicant must timely file one of the following replies: (1) an amendment, affidavit, or other evidence, which places the application in condition for allowance; (2) a Notice of Appeal (with appeal fee) in compliance with 37 CFR 41.31; or (3) a Request for Continued Examination (RCE) in compliance with 37 CFR 1.114. The reply must be filed within one of the following time periods:

- a) ☐ The period for reply expires _____ months from the mailing date of the final rejection.
- b) ☒ The period for reply expires on: (1) the mailing date of this Advisory Action, or (2) the date set forth in the final rejection, whichever is later. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of the final rejection.

Examiner Note: If box 1 is checked, check either box (a) or (b). ONLY CHECK BOX (b) WHEN THE FIRST REPLY WAS FILED WITHIN TWO MONTHS OF THE FINAL REJECTION. See MPEP 706.07(f).

Extensions of time may be obtained under 37 CFR 1.136(a). The date on which the petition under 37 CFR 1.136(a) and the appropriate extension fee have been filed is the date for purposes of determining the period of extension and the corresponding amount of the fee. The appropriate extension fee under 37 CFR 1.17(a) is calculated from: (1) the expiration date of the shortened statutory period for reply originally set in the final Office action; or (2) as set forth in (b) above, if checked. Any reply received by the Office later than three months after the mailing date of the final rejection, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

NOTICE OF APPEAL

2. ☐ The Notice of Appeal was filed on _____. A brief in compliance with 37 CFR 41.37 must be filed within two months of the date of filing the Notice of Appeal (37 CFR 41.37(a)), or any extension thereof (37 CFR 41.37(e)), to avoid dismissal of the appeal. Since a Notice of Appeal has been filed, any reply must be filed within the time period set forth in 37 CFR 41.37(a).

AMENDMENTS

3. ☐ The proposed amendment(s) filed after a final rejection, but prior to the date of filing a brief, will not be entered because
- (a) ☐ They raise new issues that would require further consideration and/or search (see NOTE below);
- (b) ☐ They raise the issue of new matter (see NOTE below);
- (c) ☐ They are not deemed to place the application in better form for appeal by materially reducing or simplifying the issues for appeal; and/or
- (d) ☐ They present additional claims without canceling a corresponding number of finally rejected claims.

NOTE: _____. (See 37 CFR 1.116 and 41.33(a)).

4. ☐ The amendments are not in compliance with 37 CFR 1.121. See attached Notice of Non-Compliant Amendment (PTOL-324).
5. ☐ Applicant's reply has overcome the following rejection(s): _____.
6. ☐ Newly proposed or amended claim(s) _____ would be allowable if submitted in a separate, timely filed amendment canceling the non-allowable claim(s).
7. ☒ For purposes of appeal, the proposed amendment(s): a) ☐ will not be entered, or b) ☒ will be entered and an explanation of how the new or amended claims would be rejected is provided below or appended.
- The status of the claim(s) is (or will be) as follows:
- Claim(s) allowed: _____.
- Claim(s) objected to: _____.
- Claim(s) rejected: 56,69-71,76 and 78.
- Claim(s) withdrawn from consideration: _____.

AFFIDAVIT OR OTHER EVIDENCE

8. ☐ The affidavit or other evidence filed after a final action, but before or on the date of filing a Notice of Appeal will not be entered because applicant failed to provide a showing of good and sufficient reasons why the affidavit or other evidence is necessary and was not earlier presented. See 37 CFR 1.116(e).
9. ☐ The affidavit or other evidence filed after the date of filing a Notice of Appeal, but prior to the date of filing a brief, will not be entered because the affidavit or other evidence failed to overcome all rejections under appeal and/or appellant fails to provide a showing a good and sufficient reasons why it is necessary and was not earlier presented. See 37 CFR 41.33(d)(1).
10. ☐ The affidavit or other evidence is entered. An explanation of the status of the claims after entry is below or attached.

REQUEST FOR RECONSIDERATION/OTHER

11. ☒ The request for reconsideration has been considered but does NOT place the application in condition for allowance because:
See Continuation Sheet.
12. ☐ Note the attached Information *Disclosure Statement*(s). (PTO/SB/08) Paper No(s). _____
13. ☐ Other: _____.

/Bridget E Bunner/
Primary Examiner, Art Unit 1647

Continuation of 11. does NOT place the application in condition for allowance because: Applicants argue that Examiner has dismissed Applicants' argument that based on Ritz, that the skilled worker would not expect a synergistic effect by combining BMP and ACE inhibitors. Further, Applicants argue the fact that Applicants are claiming a composition and not a method is irrelevant because the prior art does not teach that combining BMP morphogens and ACE inhibitors results in a synergistic reduction of proteinuria levels in a patient with diabetic neuropathy. They cite In re Soni stating that "[e]vidence of unexpected results includes evidence of synergism."

First, looking at In re Soni, the fact patterns are different between that case and the instant one. The Soni claims are product by process claims that result in a physical/structural difference that imparts greater tensile strength etc., whereas the instant claims are drawn to compositions already known in the art that when administered together improve proteinuria in a synergistic fashion. Applicants have provided no citation from In re Soni nor do they explain how this decision supports Applicants' arguments. Second, the Soni claims recite a specific molecular weight of the polymer in the claims, whereas the instant claims, which are still broad, and not drawn to any particular BMP or ACE inhibitor and do not recite any concentration/amount of the proteins. For instance, the specification teaches a dose of 10micrograms/kg of BMPs, however, this is in the same range as is taught by Sampath et al. Further, the dose of ACE inhibitors disclosed in the instant specification is the general dose administered for this drug. If Applicants' claims recite evidence of an unexpected dose or concentration that resulted in the surprising results, that would distinguish over the prior art. Note, however, the independent claims are drawn to any BMP and any ACE inhibitor, so the evidence of synergism presented by Applicants is not commensurate in scope with the claims.

Third, the only remarks made in In re Soni with regard to synergism were found by the Examiner in the dissenting opinion text:

"One way for an applicant to satisfy the burden of coming forward with evidence to rebut the prima facie case of obviousness is to demonstrate that the claimed invention yields unexpected results. In re Davies , 475 F.2d 667, 670, 177 USPQ 381, 384 (CCPA 1973). As In re Lindner makes clear, the applicant's rebuttal evidence of unexpectedness must be objective:

The affidavit and specification do contain allegations that synergistic results are obtained with all the claimed compositions, but . . . mere lawyers' arguments unsupported by factual evidence are insufficient to establish unexpected results. Likewise, mere conclusory statements in the specification and affidavits are entitled to little weight when the Patent Office questions the efficacy of those statements. . . . [W]e agree with the board that there is insufficient evidence to overcome the case of prima facie obviousness found to exist here.

Note that these remarks do not support Applicants' position, but rather the dissenting opinion states that mere allegations of synergistic results obtained with the claimed compositions are not sufficient to support a claim of non-obviousness. As set forth in the previous Office Actions, in view of the teachings of the prior art, it appears obvious that one of ordinary skill in the art would combine the BMPs and ACE inhibitors.